DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097

May 22, 2001

WARNING LETTER
CIN-WL-7007-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Rodney Belden, President
O.E. Meyer & Sons
2016 Milan Road
Sandusky, OH 44870

Dear Mr. Belden:

On March 20, 2001 and April 27, 2001, inspections were conducted of your medical gas facility, at 3303 Tiffin Avenue, Sandusky, OH. These inspections covered your manufacture of Oxygen USP (liquid and compressed gas), Nitrogen NF and Medical Air USP compressed gases. The April 27, 2001 inspection also covered your distribution controls for these and various other medical and industrial gases.

During these inspections, our investigator documented serious deviations from current Good Manufacturing Practices. These deviations cause your medical gases to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

Specific observations made during the Inspection include:

1) No written delivery reconciliation procedures established to assure customer medical gas orders are accurately filled with the correct gases and to investigate any discrepancies in deliveries.

2) No procedures in place to inspect and investigate dewars/cylinders upon return for missing or altered valves. (All dewar connections are currently soldered to help prevent manipulation.)

3) Medical and industrial gases are not segregated on the delivery trucks.

4) Employees have not been trained in medical gas reconciliation to verify that appropriate gases have been delivered, nor have they been trained to inspect valves to assure they have not been replaced or altered.

5) No written analytical procedures have been established and validated to cover Nitrogen N.F. testing of the bulk supply tank and Nitrogen content of compressed medical air. (Note: If a non-compendial method is used the method must be validated and shown to be equal or superior to the official method.)

6) Medical Air USP is filled from a swing-arm control panel connected to multiple stand-tanks (Oxygen and Nitrogen). Procedures and batch records do not indicated that a second visual check is performed to verify the proper gas mixtures are added to Medical Air USP.

7) Both industrial and medical liquid gas dewars, distributed from your facility, fail to have either a 360 degree wrap around label or identity labels at each inlet/outlet fitting. These labels are needed to provide additional assurance that the gases will not be mixed-up at the end user.

The following observations were observed during the 3/20/01 inspection but were determined to have been corrected during the subsequent 4/27/01 inspection:

1) Failure to test incoming liquid Nitrogen NF for identity and strength.

2) Failure to analyze Nitrogen NF and Medical Air USP finished products for nitrogen (identity and strength).

While these two observations were corrected other serious deficiencies observations remain uncorrected as described above.

The above described violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that you adhere to all current regulations applicable to your operations. Until these violations are corrected, Federal agencies will be informed that FDA recommends against award of contracts for affected products.

You should take prompt action to correct these violations. Failure to achieve prompt correction may result in regulatory action without further notice. These include seizure and/or injunction.

Please advise us in writing within fifteen (15) working days of receipt of this letter of the specific actions you are taking to correct these violations. Your response should explain each step you have taken to correct the noted violations, including steps taken to prevent recurrence of similar violations. Include any documentation showing these corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237-3097, to the attention of Charles S. Price, Compliance Officer. Any questions regarding this letter may be directed to Mr. Price at telephone (513) 679-2700 extension 165.

Sincerely,

Henry L. Fielden
District Director
Cincinnati District